

# PACKAGE LEAFLET: INFORMATION FOR THE USER

## COVERSYL® ARGININE 5MG FILM-COATED TABLETS

### perindopril arginine

#### Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### In this leaflet:

1. What COVERSYL ARGININE is and what it is used for
2. Before you take COVERSYL ARGININE
3. How to take COVERSYL ARGININE
4. Possible side effects
5. How to store COVERSYL ARGININE
6. Further information

#### 1. WHAT COVERSYL ARGININE IS AND WHAT IT IS USED FOR

COVERSYL ARGININE is an angiotensin converting enzyme (ACE) inhibitor. These work by widening the blood vessels, which makes it easier for your heart to pump blood through them.

##### COVERSYL ARGININE is used:

- to treat high blood pressure (hypertension),
- to treat heart failure (a condition where the heart is unable to pump enough blood to meet the body's needs),
- to reduce the risk of cardiac events, such as heart attack, in patients with stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) and who have already had a heart attack and/or an operation to improve the blood supply to the heart by widening the vessels that supply it.

#### 2. BEFORE YOU TAKE COVERSYL ARGININE

##### Do not take COVERSYL ARGININE

- if you are allergic (hypersensitive) to perindopril, to any other ACE inhibitor or to any of the other ingredients of COVERSYL ARGININE.
- if you are more than 3 months pregnant. (It is also better to avoid COVERSYL ARGININE in early pregnancy – see pregnancy section.)
- if you have experienced symptoms such as wheezing, swelling of the face, tongue or throat, intense itching or severe skin rashes with previous ACE inhibitor treatment or if you or a member of your family have had these symptoms in any other circumstances (a condition called angioedema).

##### Take special care with COVERSYL ARGININE

If any of the following apply to you please talk to your doctor before taking COVERSYL ARGININE:

- if you have aortic stenosis (narrowing of the main blood vessel leading from the heart) or hypertrophic cardiomyopathy (heart muscle disease) or renal artery stenosis (narrowing of the artery supplying the kidney with blood),
- if you have any other heart problems,
- if you have liver problems,
- if you have kidney problems or if you are receiving dialysis,
- if you suffer from a collagen vascular disease (disease of the connective tissue) such as systemic lupus erythematosus or scleroderma,
- if you have diabetes,
- if you are on a salt restricted diet or use salt substitutes which contain potassium,
- if you are to undergo anaesthesia and/or major surgery,
- if you are to undergo LDL apheresis (which is removal of cholesterol from your blood by a machine),
- if you are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings,
- if you have recently suffered from diarrhoea or vomiting or are dehydrated,
- if you have been told by your doctor that you have an intolerance to some sugars.

You must tell your doctor if you think you are (or might become) pregnant. COVERSYL ARGININE is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

COVERSYL ARGININE is not recommended for use in children and adolescents.

#### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Treatment with COVERSYL ARGININE can be affected by other medicines. These include:

- other medicines for high blood pressure, including diuretics (medicines which increase the amount of urine produced by the kidneys),
- potassium-sparing diuretics (spironolactone, triamterene, amiloride), potassium supplements or potassium-containing salt substitutes,
- lithium for mania or depression,
- non-steroidal anti-inflammatory drugs (e.g. ibuprofen) for pain relief or high dose aspirin,
- medicines to treat diabetes (such as insulin or metformin),
- medicines to treat mental disorders such as depression, anxiety, schizophrenia etc (e.g. tricyclic antidepressants, antipsychotics),
- immunosuppressants (medicines which reduce the defence mechanism of the body) used for the treatment of auto-immune disorders or following transplant surgery (e.g. ciclosporin),
- allopurinol (for the treatment of gout),
- procainamide (for the treatment of an irregular heart beat),
- vasodilators including nitrates (products that make the blood vessels become wider),
- heparin (medicines used to thin blood),
- medicines used for the treatment of low blood pressure, shock or asthma (e.g. ephedrine, noradrenaline or adrenaline).

#### Taking COVERSYL ARGININE with food and drink

It is preferable to take COVERSYL ARGININE before a meal.

#### Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

##### Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking COVERSYL ARGININE before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of COVERSYL ARGININE. COVERSYL ARGININE is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

##### Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. COVERSYL ARGININE is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

##### Driving and using machines

COVERSYL ARGININE usually does not affect alertness but dizziness or weakness due to low blood pressure may occur in certain patients.

If you are affected in this way, your ability to drive or to operate machinery may be impaired.

#### Important information about some of the ingredients of COVERSYL ARGININE

COVERSYL ARGININE contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

#### 3. HOW TO TAKE COVERSYL ARGININE

Always take COVERSYL ARGININE exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure. Swallow your tablet with a glass of water, preferably at the same time each day, in the morning, before a meal. Your doctor will decide on the correct dose for you.

The usual dosages are as follows:

**High blood pressure:** the usual starting and maintenance dose is 5 mg once daily. After one month, this can be increased to 10 mg once a day if required. 10 mg a day is the maximum recommended dose for high blood pressure.

If you are 65 or older, the usual starting dose is 2.5 mg once a day. After a month this can be increased to 5 mg once a day and then if necessary to 10 mg once daily.

**Heart failure:** the usual starting dose is 2.5 mg once daily. After two weeks, this can be increased to 5 mg once a day, which is the maximum recommended dose for heart failure.

**Stable coronary artery disease:** the usual starting dose is 5 mg once daily. After two weeks, this can be increased to 10 mg once daily, which is the maximum recommended dose in this indication.  
If you are 65 or older, the usual starting dose is 2.5 mg once a day. After a week this can be increased to 5 mg once a day and after a further week to 10 mg once daily.

#### **If you take more COVERSYL ARGININE than you should**

If you take too many tablets, contact your nearest accident and emergency department or tell your doctor immediately. The most likely effect in case of overdose is low blood pressure which can make you feel dizzy or faint. If this happens, lying down with the legs raised can help.

#### **If you forget to take COVERSYL ARGININE**

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of COVERSYL ARGININE, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking COVERSYL ARGININE**

As the treatment with COVERSYL ARGININE is usually life-long, you should discuss with your doctor before stopping this medicinal product. If you have any further questions on the use of this product, ask your doctor or pharmacist.

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, COVERSYL ARGININE can cause side effects, although not everybody gets them.

**If you experience any of the following, stop taking the medicinal product at once and tell your doctor immediately:**

- swelling of the face, lips, mouth, tongue or throat, difficulty in breathing,
- severe dizziness or fainting,
- unusual fast or irregular heart beat.

In decreasing order of frequency, side effects can include:

- Common (occur in fewer than 1 in 10 users but in more than 1 in 100 users): headache, dizziness, vertigo, pins and needles, vision disturbances, tinnitus (sensation of noises in the ears), light-headedness due to low blood pressure, cough, shortness of breath, gastro-intestinal disorders (nausea, vomiting, abdominal pain, taste disturbances, dyspepsia or difficulty of digestion, diarrhoea, constipation), allergic reactions (such as skin rashes, itching), muscle cramps, feeling of tiredness,
- Uncommon (occur in fewer than 1 in 100 users but in more than 1 in 1000 users): mood swings, sleep disturbances, bronchospasm (tightening of the chest, wheezing and shortness of breath), dry mouth, angioedema (symptoms such as wheezing, swelling of the face, tongue or throat, intense itching or severe skin rashes), kidney problems, impotence, sweating,
- Very rare (occur in fewer than 1 in 10,000 users): confusion, cardiovascular disorders (irregular heart beat, angina, heart attack and stroke), eosinophilic pneumonia (a rare type of pneumonia), rhinitis (blocked up or runny nose), erythema multiforme, disorders of the blood, pancreas or liver.
- In case of diabetic patients, hypoglycaemia (very low blood sugar level) can occur.
- Vasculitis (inflammation of blood vessels) have been reported.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### **5. HOW TO STORE COVERSYL ARGININE**

Keep out of the reach and sight of children.

Do not use COVERSYL ARGININE after the expiry date (Exp) which is stated on the carton and bottle.

The expiry date refers to the last day of that month.

Keep the bottle tightly closed in order to protect from moisture.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.


### **6. FURTHER INFORMATION**

#### **What COVERSYL ARGININE 5MG contains**

- The active substance is perindopril arginine. One film-coated tablet contains 3.395 mg perindopril (corresponding to 5 mg perindopril arginine).

The other ingredients in the tablet core are: lactose monohydrate, magnesium stearate, maltodextrin, hydrophobic colloidal silica, sodium starch glycolate (type A), and in the tablet film-coating: glycerol, hypromellose, copper chlorophyllin, macrogol 6000, magnesium stearate, titanium dioxide

#### **What COVERSYL ARGININE 5MG looks like and contents of the pack**

COVERSYL ARGININE 5 mg tablets are light-green, rod-shaped film-coated tablets engraved with  on one face and scored on both edges. The tablet can be divided into equal halves.

The tablets are available in bottles of 30 tablets.

#### **Parallel Product Authorisation Holder and Manufacturer: Product procured from within the EU by the Parallel Product**

##### **Authorisation Holder:**

IMED Healthcare Ltd  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

##### **Manufacturer:**

Anpharm Przedsiębiorstwo Farmaceutyczne S.A.,  
Ul. Annopol 6B  
03-236 Warszawa  
Poland

##### **Repackaged by:**

IMED Pharma Ltd  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

#### **This medicinal product is authorised in the Member States of the EEA under the following names:**

Austria Coversum-Arginin 5 mg -Filmtabletten  
Belgium COVERSYL 5 mg  
Cyprus COVERSYL 5 mg  
Czech Republic Prestarium Neo  
Denmark COVERSYL NOVUM 5 mg  
Estonia Prestarium Arginine 5 mg  
Finland COVERSYL NOVUM 5 mg  
France COVERSYL 5 mg  
Germany COVERSUM Arginin 5 mg  
Greece COVERSYL 5 mg  
Hungary ARMIX Arginin 5 mg  
Iceland COVERSYL NOVUM 5 mg  
Ireland COVERSYL Arginine 5 mg film-coated tablets  
Italy COVERSYL 5 mg  
Latvia PRESTARIUM 5 mg  
Lithuania PRESTARIUM 5 mg  
Luxembourg COVERSYL 5 mg  
Malta COVERSYL 5 mg  
Netherlands COVERSYL arg 5 mg  
Norway PERINDOPRILARGININ SERVIER 5 mg  
Poland PRESTARIUM 5 mg  
Portugal COVERSYL 5 mg  
Slovakia PRESTARIUM A 5 mg  
Slovenia BIOPREXANIL 5 mg  
Spain COVERSYL 5 mg  
Sweden COVERSYL NOVUM 5 mg  
United Kingdom COVERSYL Arginine 5 mg

COVERSYL is a registered trademark of Biofarma.

Date of last revision: February 2011.

## COVERSYL® ARGININE 5MG FILM-COATED TABLETS

### perindopril arginine

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- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- The name of this product in Hungary is Coverex®-AS.

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#### 1. WHAT COVERSYL ARGININE IS AND WHAT IT IS USED FOR

COVERSYL ARGININE is an angiotensin converting enzyme (ACE) inhibitor. These work by widening the blood vessels, which makes it easier for your heart to pump blood through them.

##### COVERSYL ARGININE is used:

- to treat high blood pressure (hypertension),
- to treat heart failure (a condition where the heart is unable to pump enough blood to meet the body's needs),
- to reduce the risk of cardiac events, such as heart attack, in patients with stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) and who have already had a heart attack and/or an operation to improve the blood supply to the heart by widening the vessels that supply it.

#### 2. BEFORE YOU TAKE COVERSYL ARGININE

##### Do not take COVERSYL ARGININE

- if you are allergic (hypersensitive) to perindopril, to any other ACE inhibitor or to any of the other ingredients of COVERSYL ARGININE.
- if you are more than 3 months pregnant. (It is also better to avoid COVERSYL ARGININE in early pregnancy – see pregnancy section.)
- if you have experienced symptoms such as wheezing, swelling of the face, tongue or throat, intense itching or severe skin rashes with previous ACE inhibitor treatment or if you or a member of your family have had these symptoms in any other circumstances (a condition called angioedema).

##### Take special care with COVERSYL ARGININE

If any of the following apply to you please talk to your doctor before taking COVERSYL ARGININE:

- if you have aortic stenosis (narrowing of the main blood vessel leading from the heart) or hypertrophic cardiomyopathy (heart muscle disease) or renal artery stenosis (narrowing of the artery supplying the kidney with blood),
- if you have any other heart problems,
- if you have liver problems,
- if you have kidney problems or if you are receiving dialysis,
- if you suffer from a collagen vascular disease (disease of the connective tissue) such as systemic lupus erythematosus or scleroderma,
- if you have diabetes,
- if you are on a salt restricted diet or use salt substitutes which contain potassium,
- if you are to undergo anaesthesia and/or major surgery,
- if you are to undergo LDL apheresis (which is removal of cholesterol from your blood by a machine),
- if you are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings,
- if you have recently suffered from diarrhoea or vomiting or are dehydrated,
- if you have been told by your doctor that you have an intolerance to some sugars.

You must tell your doctor if you think you are **(or might become)** pregnant. COVERSYL ARGININE is not recommended in early pregnancy, and must not be taken if you are more than 3 months

pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

COVERSYL ARGININE is not recommended for use in children and adolescents.

#### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Treatment with COVERSYL ARGININE can be affected by other medicines. These include:

- other medicines for high blood pressure, including diuretics (medicines which increase the amount of urine produced by the kidneys),
- potassium-sparing diuretics (spironolactone, triamterene, amiloride), potassium supplements or potassium-containing salt substitutes,
- lithium for mania or depression,
- non-steroidal anti-inflammatory drugs (e.g. ibuprofen) for pain relief or high dose aspirin,
- medicines to treat diabetes (such as insulin or metformin),
- medicines to treat mental disorders such as depression, anxiety, schizophrenia etc (e.g. tricyclic antidepressants, antipsychotics),
- immunosuppressants (medicines which reduce the defence mechanism of the body) used for the treatment of auto-immune disorders or following transplant surgery (e.g. ciclosporin),
- allopurinol (for the treatment of gout),
- procainamide (for the treatment of an irregular heart beat),
- vasodilators including nitrates (products that make the blood vessels become wider),
- heparin (medicines used to thin blood),
- medicines used for the treatment of low blood pressure, shock or asthma (e.g. ephedrine, noradrenaline or adrenaline).

#### Taking COVERSYL ARGININE with food and drink

It is preferable to take COVERSYL ARGININE before a meal.

#### Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

##### Pregnancy

You must tell your doctor if you think you are **(or might become)** pregnant. Your doctor will normally advise you to stop taking COVERSYL ARGININE before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of COVERSYL ARGININE. COVERSYL ARGININE is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

##### Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. COVERSYL ARGININE is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

##### Driving and using machines

COVERSYL ARGININE usually does not affect alertness but dizziness or weakness due to low blood pressure may occur in certain patients. If you are affected in this way, your ability to drive or to operate machinery may be impaired.

#### Important information about some of the ingredients of COVERSYL ARGININE

COVERSYL ARGININE 5MG contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

#### 3. HOW TO TAKE COVERSYL ARGININE

Always take COVERSYL ARGININE exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Swallow your tablet with a glass of water, preferably at the same time each day, in the morning, before a meal. Your doctor will decide on the correct dose for you.

The usual dosages are as follows:

**High blood pressure:** the usual starting and maintenance dose is 5 mg once daily. After one month, this can be increased to 10 mg once a day if required. 10 mg a day is the maximum recommended dose for high blood pressure.

If you are 65 or older, the usual starting dose is 2.5 mg once a day.

After a month this can be increased to 5 mg once a day and then if necessary to 10 mg once daily.

**Heart failure:** the usual starting dose is 2.5 mg once daily. After two weeks, this can be increased to 5 mg once a day, which is the maximum recommended dose for heart failure.

**Stable coronary artery disease:** the usual starting dose is 5 mg once daily. After two weeks, this can be increased to 10 mg once daily, which is the maximum recommended dose in this indication.

If you are 65 or older, the usual starting dose is 2.5 mg once a day.

After a week this can be increased to 5 mg once a day and after a further week to 10 mg once daily.

#### **If you take more COVERSYL ARGININE than you should**

If you take too many tablets, contact your nearest accident and emergency department or tell your doctor immediately. The most likely effect in case of overdose is low blood pressure which can make you feel dizzy or faint. If this happens, lying down with the legs raised can help.

#### **If you forget to take COVERSYL ARGININE**

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of COVERSYL ARGININE, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking COVERSYL ARGININE**

As the treatment with COVERSYL ARGININE is usually life-long, you should discuss with your doctor before stopping this medicinal product. If you have any further questions on the use of this product, ask your doctor or pharmacist.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, COVERSYL ARGININE can cause side effects, although not everybody gets them.

**If you experience any of the following, stop taking the medicinal product at once and tell your doctor immediately:**

- swelling of the face, lips, mouth, tongue or throat, difficulty in breathing,
- severe dizziness or fainting,
- unusual fast or irregular heart beat.

In decreasing order of frequency, side effects can include:

- Common (occur in fewer than 1 in 10 users but in more than 1 in 100 users): headache, dizziness, vertigo, pins and needles, vision disturbances, tinnitus (sensation of noises in the ears), light-headedness due to low blood pressure, cough, shortness of breath, gastro-intestinal disorders (nausea, vomiting, abdominal pain, taste disturbances, dyspepsia or difficulty of digestion, diarrhoea, constipation), allergic reactions (such as skin rashes, itching), muscle cramps, feeling of tiredness,
- Uncommon (occur in fewer than 1 in 100 users but in more than 1 in 1000 users): mood swings, sleep disturbances, bronchospasm (tightening of the chest, wheezing and shortness of breath), dry mouth, angioedema (symptoms such as wheezing, swelling of the face, tongue or throat, intense itching or severe skin rashes), kidney problems, impotence, sweating,
- Very rare (occur in fewer than 1 in 10,000 users): confusion, cardiovascular disorders (irregular heart beat, angina, heart attack and stroke), eosinophilic pneumonia (a rare type of pneumonia), rhinitis (blocked up or runny nose), erythema multiforme, disorders of the blood, pancreas or liver.
- In case of diabetic patients, hypoglycaemia (very low blood sugar level) can occur.
- Vasculitis (inflammation of blood vessels) have been reported.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **5. HOW TO STORE COVERSYL ARGININE**

Keep out of the reach and sight of children.

Do not use COVERSYL ARGININE after the expiry date which is stated on the carton and bottle.

The expiry date refers to the last day of that month.

Keep the bottle tightly closed in order to protect from moisture.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.


#### **6. FURTHER INFORMATION**

##### **What COVERSYL ARGININE 5MG contains**

- The active substance is perindopril arginine. One film-coated tablet contains 3.395 mg perindopril (corresponding to 5 mg perindopril arginine)

- The other ingredients in the tablet core are: lactose monohydrate, magnesium stearate, maltodextrin, hydrophobic colloidal silica, sodium starch glycolate (type A), and in the tablet film-coating: glycerol, hypromellose, copper chlorophyllin, macrogol 6000, magnesium stearate, titanium dioxide

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The tablets are available in bottles of 30 tablets.

#### **Parallel Product Authorisation Holder and Manufacturer: Product procured from within the EU by the Parallel Product Authorisation Holder:**

iMed Healthcare Ltd.  
Unit 625 Kilshane Avenue,  
Northwest Business Park  
Ballycoolin, Dublin 15  
Ireland

#### **Manufacturer:**

Les Laboratoires Servier Industrie  
905 route de Saran  
45520 Gidy - France  
Servier (Ireland) Industries Ltd  
Gorey Road  
Arklow - Co. Wicklow - Ireland  
EGIS Gyógyszergyár Nyrt.  
1106 Budapest Keresztúri út 30-38.  
Hungary  
EGIS Gyógyszergyár Nyrt.  
Lacta Gyógyszergyár  
H-9900 Körmen, Mátyás király u. 65.  
Hungary

#### **Repackaged by:**

iMed Pharma Ltd.  
Unit 625 Kilshane Avenue,  
Northwest Business Park  
Ballycoolin, Dublin 15  
Ireland

#### **This medicinal product is authorised in the Member States of the EEA under the following names:**

Austria Coversum-Arginin 5 mg -Filmtabletten  
Belgium COVERSYL 5 mg  
Cyprus COVERSYL 5 mg  
Czech Republic Prestarium Neo  
Denmark COVERSYL NOVUM 5 mg  
Estonia Prestarium Arginine 5 mg  
Finland COVERSYL NOVUM 5 mg  
France COVERSYL 5 mg  
Germany COVERSUM Arginin 5 mg  
Greece COVERSYL 5 mg  
Hungary ARMIX Arginin 5 mg  
Iceland COVERSYL NOVUM 5 mg  
Ireland COVERSYL Arginine 5 mg film-coated tablets  
Italy COVERSYL 5 mg  
Latvia PRESTARIUM 5 mg  
Lithuania PRESTARIUM 5 mg  
Luxembourg COVERSYL 5 mg  
Malta COVERSYL 5 mg  
Netherlands COVERSYL arg 5 mg  
Norway PERINDOPRILARGININ SERVIER 5 mg  
Poland PRESTARIUM 5 mg  
Portugal COVERSYL 5 mg  
Slovakia PRESTARIUM A 5 mg  
Slovenia BIOPREXANIL 5 mg  
Spain COVERSYL 5 mg  
Sweden COVERSYL NOVUM 5 mg  
United Kingdom COVERSYL Arginine 5 mg

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### perindopril arginine

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- if you are to undergo LDL apheresis (which is removal of cholesterol from your blood by a machine),
- if you are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings,
- if you have recently suffered from diarrhoea or vomiting or are dehydrated,
- if you have been told by your doctor that you have an intolerance to some sugars.

You must tell your doctor if you think you are (or might become) pregnant. COVERSYL ARGININE is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

COVERSYL ARGININE is not recommended for use in children and adolescents.

#### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Treatment with COVERSYL ARGININE can be affected by other medicines.

These include:

- other medicines for high blood pressure, including diuretics (medicines which increase the amount of urine produced by the kidneys),
- potassium-sparing diuretics (spironolactone, triamterene, amiloride),
- potassium supplements or potassium-containing salt substitutes,
- lithium for mania or depression,
- non-steroidal anti-inflammatory drugs (e.g. ibuprofen) for pain relief or high dose aspirin,
- medicines to treat diabetes (such as insulin or metformin),
- medicines to treat mental disorders such as depression, anxiety, schizophrenia etc (e.g. tricyclic antidepressants, antipsychotics),
- immunosuppressants (medicines which reduce the defence mechanism of the body) used for the treatment of auto-immune disorders or following transplant surgery (e.g. ciclosporin),
- allopurinol (for the treatment of gout),
- procainamide (for the treatment of an irregular heart beat),
- vasodilators including nitrates (products that make the blood vessels become wider),
- heparin (medicines used to thin blood),
- medicines used for the treatment of low blood pressure, shock or asthma (e.g. ephedrine, noradrenaline or adrenaline).

#### Taking COVERSYL ARGININE with food and drink

It is preferable to take COVERSYL ARGININE before a meal.

#### Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

#### Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking COVERSYL ARGININE before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of COVERSYL ARGININE. COVERSYL ARGININE is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

#### Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. COVERSYL ARGININE is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

#### Driving and using machines

COVERSYL ARGININE usually does not affect alertness but dizziness or weakness due to low blood pressure may occur in certain patients.

If you are affected in this way, your ability to drive or to operate machinery may be impaired.

#### Important information about some of the ingredients of COVERSYL ARGININE

COVERSYL ARGININE contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### 3. HOW TO TAKE COVERSYL ARGININE

Always take COVERSYL ARGININE exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

Swallow your tablet with a glass of water, preferably at the same time each day, in the morning, before a meal. Your doctor will decide on the correct dose for you.

The usual dosages are as follows:

**High blood pressure:** the usual starting and maintenance dose is 5 mg once daily. After one month, this can be increased to 10 mg once a day if required. 10 mg a day is the maximum recommended dose for high blood pressure.

If you are 65 or older, the usual starting dose is 2.5 mg once a day.

After a month this can be increased to 5 mg once a day and then if necessary to 10 mg once daily.

**Heart failure:** the usual starting dose is 2.5 mg once daily. After two

weeks, this can be increased to 5 mg once a day, which is the maximum recommended dose for heart failure.

*Stable coronary artery disease:* the usual starting dose is 5 mg once daily. After two weeks, this can be increased to 10 mg once daily, which is the maximum recommended dose in this indication.

If you are 65 or older, the usual starting dose is 2.5 mg once a day.

After a week this can be increased to 5 mg once a day and after a further week to 10 mg once daily.

#### **If you take more COVERSYL ARGININE than you should**

If you take too many tablets, contact your nearest accident and emergency department or tell your doctor immediately. The most likely effect in case of overdose is low blood pressure which can make you feel dizzy or faint. If this happens, lying down with the legs raised can help.

#### **If you forget to take COVERSYL ARGININE**

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of COVERSYL ARGININE, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking COVERSYL ARGININE**

As the treatment with COVERSYL ARGININE is usually life-long, you should discuss with your doctor before stopping this medicinal product. If you have any further questions on the use of this product, ask your doctor or pharmacist.

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, COVERSYL ARGININE can cause side effects, although not everybody gets them.

**If you experience any of the following, stop taking the medicinal product at once and tell your doctor immediately:**

- swelling of the face, lips, mouth, tongue or throat, difficulty in breathing,
- severe dizziness or fainting,
- unusual fast or irregular heart beat.

In decreasing order of frequency, side effects can include:

- Common (occur in fewer than 1 in 10 users but in more than 1 in 100 users): headache, dizziness, vertigo, pins and needles, vision disturbances, tinnitus (sensation of noises in the ears), light-headedness due to low blood pressure, cough, shortness of breath, gastro-intestinal disorders (nausea, vomiting, abdominal pain, taste disturbances, dyspepsia or difficulty of digestion, diarrhoea, constipation), allergic reactions (such as skin rashes, itching), muscle cramps, feeling of tiredness,
  - Uncommon (occur in fewer than 1 in 100 users but in more than 1 in 1000 users): mood swings, sleep disturbances, bronchospasm (tightening of the chest, wheezing and shortness of breath), dry mouth, angioedema (symptoms such as wheezing, swelling of the face, tongue or throat, intense itching or severe skin rashes), kidney problems, impotence, sweating,
  - Very rare (occur in fewer than 1 in 10,000 users): confusion, cardiovascular disorders (irregular heart beat, angina, heart attack and stroke), eosinophilic pneumonia (a rare type of pneumonia), rhinitis (blocked up or runny nose), erythema multiforme, disorders of the blood, pancreas or liver.
  - In case of diabetic patients, hypoglycaemia (very low blood sugar level) can occur.
  - Vasculitis (inflammation of blood vessels) have been reported.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### **5. HOW TO STORE COVERSYL ARGININE**

Keep out of the reach and sight of children.

Do not use COVERSYL ARGININE after the expiry date (EXP) which is stated on the carton and bottle.

The expiry date refers to the last day of that month.

Keep the bottle tightly closed in order to protect from moisture.

Medicines should not be disposed of via wastewater or household waste.


Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### **6. FURTHER INFORMATION**

#### **What COVERSYL ARGININE 5MG contains**

- The active substance is perindopril arginine. One film-coated tablet contains 3.395mg perindopril (corresponding to 5mg perindopril arginine)
- The other ingredients in the tablet core are: lactose monohydrate, magnesium stearate, maltodextrin, hydrophobic colloidal silica, sodium starch glycolate (type A), and in the tablet film-coating: glycerol, hypromellose, copper chlorophyllin, macrogol 6000, magnesium stearate, titanium dioxide

#### **What COVERSYL ARGININE 5MG looks like and contents of the pack**

COVERSYL ARGININE 5 mg tablets are light-green, rod-shaped film-coated tablets engraved with  on one face and scored on both edges. The tablet can be divided into equal halves.

The tablets are available in bottles of 30 tablets.

#### **Parallel Product Authorisation Holder and Manufacturer:**

##### **Product procured from within the EU by the Parallel Product**

##### **Authorisation Holder:**

IMED Healthcare Ltd  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

##### **Manufacturer:**

Servier (Ireland) Industries Ltd  
Gorey Road  
Arklow - Co. Wicklow – Ireland

##### **Repackaged by:**

IMED Pharma Ltd  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

#### **This medicinal product is authorised in the Member States of the EEA under the following names:**

Austria Coversum-Arginin 5 mg -Filmtabletten  
Belgium COVERSYL 5 mg  
Cyprus COVERSYL 5 mg  
Czech Republic Prestarium Neo  
Denmark COVERSYL NOVUM 5 mg  
Estonia Prestarium Arginine 5 mg  
Finland COVERSYL NOVUM 5 mg  
France COVERSYL 5 mg  
Germany COVERSUM Arginin 5 mg  
Greece COVERSYL 5 mg  
Hungary ARMIX Arginin 5 mg  
Iceland COVERSYL NOVUM 5mg  
Ireland COVERSYL Arginine 5mg film-coated tablets  
Italy COVERSYL 5 mg  
Latvia PRESTARIUM 5 mg  
Lithuania PRESTARIUM 5 mg  
Luxembourg COVERSYL 5 mg  
Malta COVERSYL 5 mg  
Netherlands COVERSYL arg 5 mg  
Norway PERINDOPRILARGININ SERVIER 5 mg  
Poland PRESTARIUM 5 mg  
Portugal COVERSYL 5 mg  
Slovakia PRESTARIUM A 5 mg  
Slovenia BIOPREXANIL 5 mg  
Spain COVERSYL 5 mg  
Sweden COVERSYL NOVUM 5 mg  
United Kingdom COVERSYL Arginine 5 mg

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